

## PATENT COOPERATION TREATY

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REC'D 13 MAY 2005

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K 2323 PCT	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US 03/41406	International filing date (day/month/year) 29.12.2003	Priority date (day/month/year) 30.01.2003	
International Patent Classification (IPC) or both national classification and IPC A61K7/16			
Applicant 3M INNOVATIVE PROPERTIES COMPANY			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
  
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
 

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.
  
3. This report contains indications relating to the following items:
  - I  Basis of the opinion
  - II  Priority
  - III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV  Lack of unity of invention
  - V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI  Certain documents cited
  - VII  Certain defects in the international application
  - VIII  Certain observations on the international application

Date of submission of the demand  16.08.2004	Date of completion of this report  17.05.2005
Name and mailing address of the International preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 TX: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Menidjel, R  Telephone No. +31 70 340-3680



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US 03/41406

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-31 as originally filed

**Claims, Numbers**

1-9 received on 10.03.2005 with letter of 10.03.2005

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US 03/41406

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-9
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US 03/41406

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.**

- The amendments filed by the applicant do not introduce subject-matter which extends beyond the content of the application as filed (Article 34(2)(b) PCT).

1. The following documents (D1,D2) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO 01/76549 A (MC LAUGHLIN GERALD) 18 October 2001 (2001-10-18)

D2: EP-A-0 363 095 (MINNESOTA MINING & MFG) 11 April 1990 (1990-04-11)

**2. Remarks - Clarity (Article 6 PCT)**

a - Claim 2 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

b - Claim 5 comprises all the features of claim 4 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

c - Claim 7 comprises all the features of claim 6 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

**3. Novelty (Article 33(2) PCT)**

- The subject-matter of present claims 1-9 appears to be novel over the cited prior art for the following reasons (Article 33(2) PCT):

- Document D1 describes a composition for whitening teeth which comprises a whitening agent and an acrylate/alpha,beta-ethylenically unsaturated dicarboxylic acid or anhydride copolymer, e.g. acrylate itaconate copolymer (Cf. D1, page 3, line 13-line 28; page 4, line 16-line 23; page 5, line 10-line 26; examples 1-5; claims 1-31).

Document D1 does not refer to a polymer comprising a repeating unit comprising a fluoride releasing group.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US 03/41406

- Document D2 describes an organic fluoride sources comprising a tetrafluoroborate salt and capable of releasing fluoride ions into dentition in order to provide inhibition and/or prevention of dental caries. The tetrafluoroborate is included in the form of a salt of an organic compound, which salt is substantially soluble in and/or polymerizable with polymerizable monomers, e.g. acrylate, methacrylate, urethane and epoxy resins (Cf. D2, page 2, line 44-page 3, line 27; page 4, line 3-line 20; page 4, line 52-page 5, line 56; page 7, line 28-line 57; claims 1-11).

Document D2 does not refers to a tooth whitening agent.

**4. Inventive Step (Article 33(1),(3) PCT)**

- Although novel, the subject-matter of present claims 1-9 cannot be considered as being inventive for the following reasons (Article 33(1),(3) PCT):

- The subjective problem to be solved by the present application is to provide a **dental whitening composition** suitable for coating oral surfaces which can be conveniently administered using simple and inexpensive equipment and lead to efficient whitening.

- The solution according to the present application consists in a dental whitening composition comprising a tooth whitening agent, a polymer comprising a repeating unit comprising a polar or polarizable group and a repeating unit comprising a fluoride releasing group, with the proviso that the polymer does not include pendant ethylenically unsaturated moieties (see present claim 1).

- Document D1, which is considered as the closest prior art, describes a composition for whitening teeth which comprises a whitening agent and an acrylate/alpha,beta-ethylenically unsaturated dicarboxylic acid or anhydride copolymer, e.g. acrylate itaconate copolymer (Cf. D1, page 3, line 13-line 28; page 4, line 16-line 23; page 5, line 10-line 26; examples 1-5; claims 1-31).

- The difference between the teaching of the closest prior art and the claimed subject-matter is a dental whitening composition suitable for coating oral surfaces comprising a polymer comprising a repeating unit comprising a repeating unit comprising a fluoride releasing group (see also Applicant's letter dated 10.03.2005, on pages 2, last paragraph-page 3, first

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US 03/41406

paragraph).

- Therefore, the objective technical problem may be seen as to provide a dental composition comprising a polymer comprising a repeating unit comprising a fluoride releasing group.
- Document D2 discloses an organic fluoride sources comprising a tetrafluoroborate salt and capable of releasing fluoride ions into dentition in order to provide inhibition and/or prevention of dental caries. The tetrafluoroborate is included in the form of a salt of an organic compound, which salt is substantially soluble in and/or polymerizable with polymerizable monomers, e.g. acrylate, methacrylate, urethane and epoxy resins.
- It would be obvious to the person skilled in the art, to apply this feature with corresponding effect to a dental composition according to document D2, to a whitening composition according to document D1, thereby arriving at a dental whitening composition suitable for coating oral surfaces according to present claims 1-9.

Consequently, the subject-matter of present claims 1-9 lacks an inventive step (Article 33(1),(3) PCT).

**5. Industrial Application (Article 33(4) PCT)**

- The subject-matter of present claims 1-9 is considered to be industrially applicable; claims 1-9 therefore, satisfy the criterion set forth in Article 33(4) PCT.

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

VOSSIUS & PARTNER  
Patentanwälte  
P.O. Box 86 07 67  
D-81634 München  
ALLEMAGNE

PCT

WRITTEN OPINION  
(PCT Rule 66)

		Date of mailing (day/month/year)	20.01.2005
Applicant's or agent's file reference K 2323 PCT		REPLY DUE	<b>within 2 month(s)</b> from the above date of mailing
International application No. PCT/US 03/41406	International filing date (day/month/year) 29.12.2003	Priority date (day/month/year) 30.01.2003	
International Patent Classification (IPC) or both national classification and IPC A61K7/16			
Applicant 3M INNOVATIVE PROPERTIES COMPANY			

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I     Basis of the opinion
  - II    Priority
  - III    Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV    Lack of unity of invention
  - V    Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI    Certain documents cited
  - VII    Certain defects in the international application
  - VIII    Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.
 

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:** For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 30.05.2005

Name and mailing address of the international preliminary examining authority:	Authorized Officer
 European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Menidjel, R Formalities officer (incl. extension of time limits) Cherqui, E Telephone No. +31 70 340-2643



**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.**

1. The following documents (D1,D2) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO 01/76549 A (MC LAUGHLIN GERALD) 18 October 2001 (2001-10-18)

D2: EP-A-0 363 095 (MINNESOTA MINING & MFG) 11 April 1990 (1990-04-11)

**2. Clarity (Article 6 PCT)**

a - It is clear from the description on pages 1,2 and 6 that the following features are essential to the definition of the invention:

a dental whitening composition suitable for coating oral surfaces comprising

(1) a tooth whitening agent;

(2) a polymer comprising a polar or polarizable group;

(3) a repeating unit comprising a fluoride releasing group (see claims 1 and 4) or a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group and combination thereof (see claims 2 and 5)

(4) with the proviso that the polymer does not include pendant ethylenically unsaturated moieties,

(5) and with the proviso that the dental whitening composition does not include hydrogen peroxide.

Since independent claims 1,2,4,5 do not contain these features, it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

Moreover, it appears that the subject-matter of present claims 1,2,4 and 5 and the corresponding parts of the description referring to this subject-matter describes a different solution to the subjective problem raised in the present application than the solution described in present claim 1. An objection of lack of unity of the present application may be raised if no amendments are done.

b - Present claim 3 and in the description on page 5, refer to tooth whitening agent selected from the group consisting of a hypochlorite,..., a hydroperoxide,..., and

combination thereof. Present claim 3 and said part of the description present some inconsistencies with what appear to be an important proviso of the present invention, namely that the dental whitening composition does not include hydrogen peroxide.

c - The expression "...publications cited herein are incorporated by reference..." found in the description like for example on page 30 should be deleted.

- As far as the claimed subject-matter can be understood in view of the unclarities mentioned above, the following is to be noted concerning novelty and inventive step:

**3. Novelty (Article 33(2) PCT)**

- The subject-matter of present claims 1-5 is considered as not novel for the following reasons (Article 33(2) PCT):

- Document D2 describes an organic fluoride sources comprising a tetrafluoroborate salt and capable of releasing fluoride ions into dentition in order to provide inhibition and/or prevention of dental caries. The tetrafluoroborate is included in the form of a salt of an organic compound, which salt is substantially soluble in and/or polymerizable with polymerizable monomers, e.g. acrylate, methacrylate, urethane and epoxy resins (Cf. D2, page 2, line 44-page 3, line 27; page 4, line 3-line 20; page 4, line 52-page 5, line 56; page 7, line 28-line 57; claims 1-11).

The subject-matter of document D2 takes away novelty of present claims 1-5.

**4. Inventive Step (Article 33(1),(3) PCT)**

- Although novel, the remaining subject-matter, which is the subject-matter of present claims 6-9 cannot be considered as being inventive for the following reasons (Article 33(1),(3) PCT):

- The subjective problem to be solved by the present application is to provide a dental whitening composition suitable for coating oral surfaces which can be conveniently administered using simple and inexpensive equipment and lead to efficient whitening.

- The solution according to the present application consists in a whitening composition comprising a tooth whitening agent, a polymer comprising a repeating unit comprising a polar or polarizable group and a repeating unit comprising a fluoride releasing group, with the proviso that the polymer does not include pendant ethylenically unsaturated moieties

(see present claim 1).

- Document D1, which is considered as the closest prior art, describes a composition for whitening teeth which comprises a whitening agent and an acrylate/alpha,beta-ethylenically unsaturated dicarboxylic acid or anhydride copolymer, e.g. acrylate itaconate copolymer (Cf. D1, page 3, line 13-line 28; page 4, line 16-line 23; page 5, line 10-line 26; examples 1-5; claims 1-31).

The difference between the teaching of the closest prior art and the claimed subject-matter appears to be the presence of a tooth whitening agent in an amount greater than 10% by weight based on the total weight of the dental whitening composition and a polymer comprising a repeating unit comprising a modulating group.

The feature of present claims 6-9 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

Consequently, the subject-matter of present claims 6-9 lacks an inventive step (Article 33(1),(3) PCT).

The applicant is requested to file new claims which take account of the above comments.

The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate. He is invited to file new claims and adapt description, in particular by deleting passages referring to aspects of the inventions which do not correspond to claimed subject-matter (Article 6 PCT).

The amendments filed by the applicant should not introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT.

**I. Basis of the opinion**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

**Description, Pages**

1-31 as originally filed

**Claims, Numbers**

1-9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
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- contained in the international application in written form.
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- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5.  This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

**WRITTEN OPINION**International application No. PCT/US 03/41406

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Novelty (N)	Claims	1-5
Inventive step (IS)	Claims	1-9
Industrial applicability (IA)	Claims	

**2. Citations and explanations****see separate sheet**